

**OPENING ADDRESS BY  
DR AMY KHOR, SENIOR MINISTER OF STATE FOR HEALTH AND  
MANPOWER AT HSA'S EXCELLENT STAKEHOLDER & PARTNERSHIP  
AWARDS  
ON 6 NOVEMBER 2013 (WED), 12PM,  
NATIONAL UNIVERSITY OF SINGAPORE SOCIETY GUILD HOUSE  
(KENT RIDGE)**

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Associate Professor John Lim,  
CEO HSA

Distinguished Award Recipients,

Ladies and Gentlemen,

Good afternoon,

1. I am pleased to join you today at the Health Sciences Authority's (HSA) inaugural Excellent Stakeholder and Partnership Awards (ESPA) Ceremony. The Awards recognise and honour the achievements of stakeholders that HSA has closely worked with over the years. Comprising distinguished healthcare experts, partner agencies and industry associations, the sixty-two (62) award winners truly reflect the diverse stakeholder segments that HSA engages to ensure that medicinal and health-related products in Singapore meet appropriate standards of safety, quality and efficacy.

**Singapore's Evolving Healthcare Landscape and Challenges**

2. Even as we celebrate such successful collaborations, our work is never truly done. Our regulatory regime must keep pace with a fast evolving healthcare and biomedical landscape where public expectations are high and unlikely to diminish in the foreseeable future. Science and technology enable many new breakthroughs. Understandably, industry players hope to leverage on these developments to market the latest products. Healthcare professionals and patients, meanwhile, desire access to the latest medical innovations. Examples include developments in genetics and molecular biology that enable more personalised treatment, and the use of nanotechnology in medical devices.

3. But, while these innovations have the potential to enhance the quality of life for patients in Singapore, there must also be safeguards to ensure the population's safety when using these new health products. This is where effective and smart regulation plays a role.

### **The Evolving Role of the Regulator**

4. Traditionally, health product regulators function as “controllers” who administer regulations through rigorous scientific review of products, and the issuance of licences for their manufacture, distribution, and sale.

5. This vigilant monitoring of product safety and enforcement will always be the cornerstone of our health products regulatory framework. However, the overall framework has to evolve to keep pace with rapid medical advances. As a regional medical hub in Asia for innovative therapeutics and technologies, Singapore's regulatory system must facilitate and enable timely access to new health products. This requires a very precise or fine balance whereby effective enforcement to secure the safety and quality of health products does not over-burden the industry with regulatory rigidities.

6. To strike this balance, the HSA has remained steadfast in reviewing, refining and developing its risk-based and adaptive regulatory frameworks. This is also better achieved by collaborating closely with all key stakeholders to promote efficiency and inclusiveness. After all, effective stakeholder engagement will enable better planned and more informed policies by addressing stakeholder concerns without compromising public health. This will also be increasingly important as HSA incrementally regulates more product types under the Health Products Act.

### **Some Award Examples**

7. The collaborative efforts of the ESPA recipients lauded today bear testament to this principle at work. Some involved successful enforcement operations which bring to justice those who flout the law and endanger public

health. For instance, multi-agency operations against peddlers of illegal sexual enhancement drugs like 'Power 1 Walnut' have curbed the prevalence of such prohibited products in the market.

8. HSA has also forged partnerships with healthcare professionals to enhance the signal detection and reporting of adverse events related to medicines. Such early detection has enabled HSA to initiate prompt investigations and regulatory actions to minimise the risk of exposure for the wider public.

9. I would like to highlight two award-winning projects which embody this spirit of close collaboration between HSA and healthcare professionals and institutions. During the 2009 H1N1 pandemic, HSA worked with the KK Women's and Children's Hospital (KKH) and the Health Promotion Board's (HPB) National Immunisation Registry to closely monitor the safety of the H1N1 vaccine when it was rolled out to the population. This was because at that time, information on the vaccine's potential side effects was lacking, especially for children and pregnant women. A sentinel site was thus set up at KKH where all vaccine adverse events were actively reported for prompt detection of any emerging safety signals. A registry of all vaccinated patients was also developed with the National Immunisation Registry for HSA to track the number of doses administered and compute the incidence rate of any adverse event. The systems piloted through such collaborations have since been adapted to monitor on-going vaccination programmes in Singapore.

10. Another successful project involved the integration of the Ministry of Health's Critical Medical Information Store (CMIS) and HSA's Pharmaceutical Regulatory Information System (PRISM) - which strengthened pharmacovigilance processes by leveraging on technology. The merged databases resulted in faster and more comprehensive detection of potential safety signals between public healthcare institutions and HSA. This initiative by a team of dedicated clinicians and pharmacists has also enabled Singapore to secure the world lead in terms of the number of valid reports per million inhabitants submitted to the World Health Organisation's (WHO) global database.

11. The 'Excellent Partnership Award', meanwhile, recognises industry and healthcare professional associations, as well as government agencies, which work closely with HSA at various local and regional platforms to discuss regulatory issues and share invaluable feedback. Such open dialogues between the associations and the regulator are commendable as they help HSA to ensure that its regulatory frameworks, processes and policies remain balanced, current and relevant.

12. A good example is HSA's engagement of the Medical Technology Industry Group of the Singapore Manufacturing Federation; the Association of Medical Device Industry (AMDI); as well as healthcare professional societies. The dialogues amongst them have helped all parties to understand the challenges each faces when developing, implementing and refining the medical device regulatory framework, especially in the last 2 years. All feedback garnered has been instrumental in helping to scope enhancements to the medical device framework since April 2012.

13. Moving forward, I hope that HSA will continue to roll out more platforms for engagement such as industry consultative panels for various health products, and presentations on new developments in product pipelines. A prime example of this was HSA's well-received Health Products Regulatory Conference in September 2013. Apart from allowing all stakeholders a first look at health products in development, such networking opportunities also allow HSA the opportunity to identify and assemble appropriate expertise to potentially speed up evaluation of new products upon submission. HSA can also leverage on such interactions with healthcare professional associations and institutions to develop more opportunities to disseminate useful regulatory information and updates.

### **Strengthening Regulatory Science**

14. Last but not least, I would like to acknowledge the growing number of outstanding and talented healthcare experts in Singapore who are passionate about their areas of expertise and willing to work with HSA to provide strong leadership and invaluable advice in HSA's scientific advisory committees. Such partnerships help to strengthen regulatory science by ensuring that HSA's

evaluations of health products are robust, holistic and take into account current clinical practice and the latest scientific developments. Singapore and Singaporeans in turn benefit from HSA's sound regulatory decisions that stand up well to review by its international regulatory counterparts, academic institutions and global industry players.

## **Conclusion**

15. In closing, I would like to take this opportunity to extend my heartiest congratulations to all the award winners for your achievements and invaluable contributions. I urge you to continue working closely with HSA as your useful views and feedback will help shape present and future policies that collectively create a well-balanced health products regulatory ecosystem for our country.

Thank you.